

K133083 DIAZYME FERRITIN ASSAY, DIAZYME FERRITIN CALIBRATOR SET, DIAZYME FERRITIN CONTROL SETJun 24, 2014
267 days to decisionK133083 · Product code: **DBF** · Immunology
Source: <https://www.510kdatabase.net/k133083/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ferritin, Antigen, Antiserum, Control (DBF)
Date received	Sep 30, 2013
Decision date	Jun 24, 2014
Days to decision	267 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Diazyme Laboratories
Location	Irvine, CA, US
Contact	Abhijit Datta
510(k) history	41 submissions · 41 cleared · 2003-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k133083/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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